EFFICACY REVIEW

Product: **P.C.Q. Pelleted Rodent Bait**

Date: May 7, 2009

EPA File Symbol: CA78014600

DP Bar code: D305173

Chemical Code(s): 067701

Formulation: 0.01% Diphacinone

Purpose for Review: The purpose for this review is to determine if the efficacy data for SLN CA780146 in response to the Rodenticide RED is acceptable.

MRID(s): **462962-02** Lindgren, B.V. April 12, 2004. Efficacy of 0.01% Diphacinone Pellets on Young Adult Swiss Webster Mice. Bell Laboratories, Inc. Unpublished Report. BEL/0304/BE530. 85pp.

Good Laboratory Practices: Yes

Branch Supervisor: Meredith Laws, Branch Chief

Team Reviewer: John Hebert, Product Manager -PM Team 07

IRB Reviewer: Geraldine R. McCann, Biologist

BACKGROUND: The original application for this 24 (c) product was made October 10, 1978, for the State of California. The parent product is EPA Reg No. 12455-19 Ditrac® Rat and Mouse Bait (registered February 3, 1978). The Ditrac® Rat and Mouse Bait has 2 alternate names: La Rat and Mouse Bait and P.C.Q. Mouse Bait. In a letter dated July 5, 1983, the Manager of Registration and Toxicology in Bethany, CT (cc EPA) received a letter of withdrawal as of June 30, 1983, for the 24 (c) product in question (CA7801460) from the California Pesticide Registration and Agricultural Productivity. The California Department of Food and Agriculture (CDFA) received a letter dated June 30, 1983, from Bell Laboratories, Inc. wishing to renew the 24 (c) product known as P.C.Q. Pelleted Rodent Bait (CA780146). The California Pesticide Registration and Agricultural Productivity granted Bell Laboratories, Inc. the renewal July 13, 1983. The label was sent in to the Registration Division September 29, 2003 for a label revision. This product is very similar to the parent product (EPA Reg No. 12455-19 Ditrac® Rat and Mouse Bait, 0.005% diphacinone), but has a higher concentration of active ingredient (0.01%). The CSFs are comparatively very similar. There are no previous efficacy reviews or evidence of reviews for new uses for this product. In a letter dated

October 27, 1978, W. H. Miller, of the RD/IRB asked the CDFA for confirmation of these reviews: "It is our opinion that this section 24 (c) registration is for a 'changed use pattern'. Please confirm whether a product hazard determination has been performed for the ground squirrel and deer mouse uses." Investigating the jacket, no evidence is present to address the missing information about the efficacy for ground squirrels and/or deer mice. Since these rodents are considered human health pests, the information requirement falls under 40 CFR 162.153 (b) *Special Local Need Determination*, (c) *Unreasonable Adverse Effects Determination*, and (d) *Efficacy Determination*.

REVIEW OF DATA:

462962-02 Lindgren, B.V. April 12, 2004. Efficacy of 0.01% Diphacinone Pellets on Young Adult Swiss Webster Mice. Bell Laboratories, Inc. Unpublished Report. BEL/0304/BE530. 85pp.

DISCUSSION:

The purpose of this study as described by Lindgren is to determine the effectiveness of an the 0.01% diphacinone pellets on laboratory mice. The test is described in the Pesticide Assessment Guideline Subdivision G: 96-10, Commensal Rodenticides, OPP Guideline 1.204 (06/18/1991): Standard House Mouse Anticoagulant Dry Bait Laboratory Test Method. The test material was manufactured by the producer and offered to Lindgren for testing purposes: Batch L2203.

This protocol dictates exposure of test-group animals to a choice between EPA rat and mouse challenge diet and a toxic anticoagulant rodenticide bait for a period of 15 days followed by 5 days of post test observation during which time EPA challenge diet is to be the only food offered. **No information other than a notation for SOP BIO001.6 (Formulation of EPA Challenge Diet) for the standard EPA rat and mouse challenge diet was offered to show Bell Laboratories prepared the challenge bait, no production date was offered, no storage placement and conditions.**

For this study, there were 2 groups of 10 males and 2 groups of 10 female Swiss Webster strain laboratory mice. Lindgren explains, 20 male and 20 female test animals were group housed (five/sex/cage) in suspended, stainless steel caging. The control groups were within the same weight category as the test animals and were group housed in similar cages. The animals were placed in an environmentally controlled room set to maintain a 12 hour light/12 hour dark cycle. Environmental controls were set to maintain a temperature of 20 °C to 25 °C with a humidity of 50 to 55% during the test. The actual humidity during the test ranged from 32% to 53%, according to the deviations listed on page 11 of 85. **No laboratory temperature or humidity raw data records are presented in this report.**

Each test animal group of five were presented with two glass jars containing

0.01% Diphacinone Pellets and two glass jars of EPA challenge diet. Each group of control animals were provided with four glass jars of EPA challenge diet. The position of the food containers was reversed daily.

The test-group males (n=10) weighed 21.6 g to 25.7 g (mean = 23.98 g) at the start of the test, while the females (n=10) weighed 18.1 g to 20.8 g (mean = 19.42 g). There was a 4.56 g difference in mean weights between the sexes of the tested groups and they were within the allowable weight range of 5 g. The control group was similarly comprised, with the males averaging 25.3 g (range 23.4 - 27.5 g) and the females 19.69 g (range 17.0 - 25.9 g) at the start of the study. Overall, the difference between all males and all females was 4.82 g. The mean body weights at death, of the male and female mice in each of the groups were 23.01 g, 17.12 g (Treated), and 22.11 g and 27.96 g (Control), respectfully. From the initial weights and during the course of the test, only three of the treated males gained weight. In the control group, all 10 of the females and only 2 of the males gained weight.

The guidelines (1.204, 6.2) recommend a "ball-type watering tube" and "Gravity fed automatic or open-cup type waterers are not recommended." An automatic watering system with 3.6 PSI was delivered to the mice. Lindgren states: "These deviations should not effect the integirty of the study or the final results."

The OPP guideline states in 1.204, 6.3: "Spilled food must be recovered and weighed to establish exact food consumption data. Where the food spillage is damp it shall be dried to approximately its original moisture content before weighing." Lindgren does not mention the bait spillage in his final report. **In the future, please submit spillage data for efficacy tests.**

The OPP guideline 1.213, 9.2 states that "The product is considered to have satisfactory bait acceptance if a minimum of 33% of the food consumed by the test group animals was the toxic bait, if at least 90% of the test group subjects die during the 20-day test, and if no more than 10% of control group subjects die during the 20-day test." The toxic bait consumption calculated by Lindgren for the bait product was 41.5% and mortality was 100%. Overall calculation of toxic bait consumption was 41.42%.

The bait-exposure phase of the bioassay began on March 8, 2004.

Results of the trial are summarized Tables 1 and 2. All test-group animals died within 3 to 13 days of the onset of exposure to toxic bait. The 90% mortality criterion for a trial with dry bait was met. No mortalities were reported for the control group.

The test results are summarized below:

Table 1. Diphacinone (0.01%) Pellets on Young Adult Swiss Webster Mice.

	Pretest Weights		**15-Day Test-Consumption and Mortality**		
Sex	**Average Group**		**OPP Diet**	**Treated Bait**	**Total Bait**

	Weight (g)	Consumed (g)	Consumed (g)	Consumption (g)
M (10)	23.98	191.3	135.8	327.1
F (10)	19.42	**100% Mortality**		Percent **Toxic Bait** Consumed 41.42%
Total (20)	Group Difference 4.56			

Table 3. Control Mouse Consumption
Pretest Weights15-Day Test-Consumption and Mortality

Sex	Average Group Weight (g)	OPP Diet Consumed (g)	Total Bait Consumption (g)
M (10)	25.03	325.0	325.0
F (10)	19.69	**0% Mortality**	
Total (20)	Group Difference 5.34		

Efficacy Comments

1. No information other than a notation for SOP BIO001.6 (Formulation of EPA Challenge Diet) for the standard EPA rat and mouse challenge diet was offered to show Bell Laboratories prepared the OPP rat and mouse challenge diet, no production date was offered, no storage placement, storage conditions, or record of storage. Please provide this information in future submissions.

2. No raw data records for daily laboratory temperature or humidity are presented in this report. Please provide this information in future submissions.

3. The OPP guideline 1.204, 6.3, states: "Spilled food must be recovered and weighed...". In the future, please submit spillage data for efficacy tests.

4. It is our opinion that this section 24 (c) registration is for a "changed use pattern" from the parent label. Investigating the jacket, no evidence is present to address the missing information about the efficacy for ground squirrels and deer mice. Since these rodents are considered human health pests, the information requirement falls under 40 CFR 162.153 (b), (c), and (d). **Please confirm whether a product hazard determination has**

been performed for the ground squirrel and deer mouse uses.

Label Review It appears that changes requested in a letter dated April 19, 2004, from D. Peacock, have been made and all efficacy related language is acceptable.

Conclusion(s): The laboratory efficacy study submitted in association with P.C.Q. Pelleted Rodent Bait (MRID number 462962-02 [BEL/0304/BE530] is acceptable pending the confirmation of acceptable efficacy reviews for ground squirrel and deer mouse studies from California. This acknowledgment is not to be construed as an EPA approval of this reregistration.